

A Motion:

Edits recommended by the Chair for the NVAC Vaccine Safety White Paper, version 3.0.

1. Clarify that NVAC chose Assurance Option 1 at its June 14 meeting.

Page 54, Lines 12-15

“...Despite extensive efforts by its members to debate and discuss the options over a period of many months, the VSWG was not able to come to a consensus on the preferred assurance option prior to the June 2011 NVAC meeting where the White Paper recommendations were discussed in detail. At this meeting, the NVAC reviewed the options developed by the VSWG and provided direction for Option 1: NVAC should continue to be the advisory entity primarily responsible for evaluating the NVP programs.

Appendix 13 - Page 118, Lines 12-14

“Three options were developed by the VSWG ~~discussed~~ for external, independent assurance ~~related to~~ of the vaccine safety system, with the second of these options having three potential configurations. The NVAC reviewed the three options at the June 2011 meeting and provided direction for Option 1: NVAC should continue to be the advisory entity primarily responsible for evaluating the NVP programs. Below is a review of the two options not selected by the NVAC for recommendation by the Committee.

2. Clarify that NVAC’s review of the safety system considered leadership, assurance and accountability in addition to coordination, corresponding to Recommendations 1, 2 and 3.

Page 4, Lines 11-14

The NVAC's review of the federal vaccine safety system concentrated on these aspects of the system to determine where opportunities for improvement exist:

- Leadership ~~Coordination of the system~~ – Direction, Coordination and integration of federal efforts relevant to immunization safety, including mechanisms to provide assurance and accountability.

3. Clarify Recommendation 1.2/correct inadvertent change from prior version.

Page 8, Lines 22-34 and Page 50, Lines 11-23

Include the IHS and the Agency for Healthcare Research and Quality (AHRQ) as participants in the NVP. Also, the Secretary should direct HHS agencies coordinated under the NVP—accompanied by a request to the DoD, the VA, and the USAID—to do the following:

- Fully participate in NVPO vaccine-safety coordination efforts.

- Identify and pursue opportunities for collaborative projects relevant to NVP vaccine safety objectives with other NVP-coordinated agencies.

- Regularly obtain the advice of appropriate subject matter experts and consumers to guide initiatives related to vaccine safety.

- Provide other governmental agencies, vaccine manufacturers, appropriate stakeholder organizations, and representatives of the public the opportunity to provide feedback regularly during the planning and implementation of initiatives related to vaccine safety, and tell them about initiatives and outcomes related to vaccine safety

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The Secretary should ~~D~~define performance expectations related to vaccine safety for NVP-coordinated agencies.

4. Other clarified wording, typographical errors and factual corrections.

Page 3, Lines 32-33: "...a meeting to obtain stakeholder input was held on June 13~~2~~, 2011..."

Page 23, Line 27-29: "One of the functions of the NVAC is to recommend research priorities and other measures the Director of the NVP should take to enhance the safety and efficacy of vaccines, hence the rationale for their undertaking the writing of this report ~~which is the subject matter of this White Paper.~~

Page 38, Lines 24-26: "...The most current ~~A-review is currently underway~~ to address changes in the Table regarding more recently recommended vaccines and adverse events potentially associated with them has just been published.^[2] ..."

Page 42, Lines 7-11: "Federal Advisory committees (e.g., the NVAC, the ACIP, the VRBPAC, the MDRAC, the Advisory Committee on Childhood Vaccines [ACCV], the Defense Health Board (DHB) ~~Armed Forces Epidemiological Board [AFEB]~~ which hold public meetings and have public representatives play a role in decision making processes regarding vaccination policy and practices (i.e. licensure alone is not sufficient for incorporation into the recommended vaccine schedule).

Page 67, Lines 21-22: "Expanded efforts to obtain information on ~~Calculation of~~ background rates of potential AEFI in subpopulations would assist in vaccine safety risk assessment.

Page 97, Line 17-19: "...A review of the Options for Accountability and Assurance deliberated on by the VSWG and presented to the Committee is provided in Appendix 132..."

Page 118, Lines 4-5: "...In completing their charge, the National Vaccine ~~Safety~~ Advisory Committee (NVAC) Vaccine Safety Working Group (VSWG) found that; in order to assure ..."